

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

REMARKS

In response to the Final Office Action mailed July 29, 2003 (hereafter referred to as "Office Action"), Applicant respectfully requests reexamination of the claims and reconsideration of the Examiner's final rejection of the claims of the above-identified application.

Claims 1-26 are pending in the Application.

No claims have been cancelled.

No claims have been withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1-3, 10, 15-18, 24, and 25 have been rejected under 35 U.S.C. § 102(b) as being unpatentable over Duffy et al. ("*Duffy*") (U.S. Patent 5,516,793). Applicant respectfully traverses the 35 U.S.C. § 102(b) rejections as such rejections pertain to the cited claims. Reconsideration of withdrawal of the rejections are respectfully requested in view of the amendments to the claims and the following remarks.

The Examiner has stated that *Duffy* expressly discloses a composition comprising demineralized water, propylene glycol, glycerin, hydroxyethylcellulose, Tween 20, ammonium hydroxide, glycolic acid and ascorbic acid (5% or 10%), having a pH of 3.7 (5%) and 3.8 (10%). The Examiner has also stated that with respect to claim 24, the term "about 15%" is not defined, as such, the Examiner has read the term "about" to include 10%. See Office Action, page 2, fourth full paragraph.

Applicant respectfully suggests that *Duffy* discloses that the use of an effective amount of ascorbic acid or one or more of its derivatives has been found to decrease skin irritation caused by the topical administration of an active ingredient for treating a skin condition. See *Duffy* Abstract. The *Duffy* invention relates to dermatologic agents which reduce irritation caused by the topical application of an active ingredient used to treat a skin condition. *Duffy* discloses that more particularly, ascorbic acid or a derivative product is added to a cosmetically and/or pharmaceutically acceptable vehicle to reduce the irritation reaction. See *Duffy*, column 1,

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

lines 10-15. *Duffy* also discloses that the *Duffy* invention is generally directed to dermatological agents which include an active ingredient used to treat a skin condition and an amount of ascorbic acid, or derivative thereof, effective for reducing irritation. *Duffy* discloses that while the *Duffy* specification is primarily directed to illustrating the *Duffy* invention with respect to active ingredients which induce irritation, it should be appreciated that irritation may be caused by the vehicle (without the ascorbic acid) or by a combination thereof. See *Duffy*, column 3, line 65-column 4, line 7.

Duffy further discloses that the presence of ascorbic acid reduces the occurrence or severity of irritation and/or provides for higher concentrations of active ingredient without causing irritation. See *Duffy*, column 4, lines 8-14. The *Duffy* composition comprises at least one inert vehicle in combination with an effective amount of ascorbic acid and/or derivative(s) thereof, formulated for topical administration of a dermatologically active ingredient. *Duffy* discloses several active ingredients such as alpha-hydroxy acids, keto acids, Vitamin A and derivatives thereof, as well as other active ingredients. See *Duffy*, column 5, lines 18-40.

Applicant respectfully suggests that *Duffy* is utilizing the ascorbic acid to reduce the irritation created by the *Duffy* active ingredient(s). In contrast, Applicant's claimed invention utilizes ascorbic acid as the active ingredient. Applicant respectfully suggests that *Duffy*'s use of the ascorbic acid to reduce the irritation of an active ingredient(s) teaches away from Applicant's claimed invention of utilizing a high concentration of ascorbic acid as an active ingredient while utilizing the novel aspects of Applicant's pH levels of Applicant's composition to reduce the irritation from the high concentration of ascorbic acid.

Applicant also respectfully suggests that: (1) the *Duffy* emphasis on the irritation of the active ingredient, or a vehicle without the ascorbic acid, or by a combination thereof, with no emphasis regarding irritation from the ascorbic acid, and (2) the *Duffy* use of the ascorbic acid to reduce the occurrence or severity of irritation of the *Duffy* active ingredient(s) further teaches away from Applicant's composition.

Applicant respectfully suggests that the description of the *Duffy* composition described in the Office Action at page 2, fourth full paragraph, is from *Duffy* Example II at column 7, lines 7-63 describing *Duffy* Compositions E and F. Applicant respectfully suggests that pH

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

levels are not emphasized in *Duffy* except for disclosing the pHs of the various compositions of Examples I and II. Applicant respectfully suggests that *Duffy* does not emphasize pH levels due to *Duffy's* reducing the irritation of the *Duffy* active ingredient(s) with the addition of the *Duffy* ascorbic acid. In contrast, Applicant's composition utilizes the ascorbic acid as the active ingredient and reduces irritation with Applicant's pH levels. Applicant respectfully suggests that the pHs disclosed for the *Duffy* compositions in Examples I and II do not anticipate, disclose, or suggest Applicant's topical composition as described in Applicant's independent claims 1, 18, and 26 and the claims depending therefrom.

Applicant also respectfully suggests that the pHs of the compositions utilized in *Duffy* Examples I and II are merely a result of the various combinations of *Duffy* ingredients utilized in the compositions. Applicant respectfully suggests that such disclosure does not disclose or suggest Applicant's use of pH levels to reduce the irritation of Applicant's concentration of ascorbic acid. Further, Applicant respectfully suggests that there is no emphasis of pH levels in *Duffy* due to the addition of the *Duffy* ascorbic acid to reduce the irritation of the *Duffy* active ingredient(s).

Applicant also respectfully suggests that the pH levels for *Duffy* Compositions A and B were approximately 2.4. *Duffy* Composition B contained 5 percent ascorbic acid as a vehicle additive. For the 20 subjects using *Duffy* Composition B, no irritation responses were recorded and none of the subjects experienced discomfort. See *Duffy*, Example I, column 6, line 40-column 7, line 6. Applicant respectfully suggests that the disclosure of *Duffy* Composition B having a pH of approximately 2.4 with no irritation response teaches away from Applicant's composition utilizing at least about 5.0% ascorbic acid wherein the composition has a pH of more than 3.5.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Schinitzky et al. ("*Schinitzky*") (U.S. Patent 4,938,969) in view of Murad ("*Murad*") (U.S. Patent 5,804,594), Herstein ("*Herstein*") (U.S. Patent 5,902,591) and Taylor et al. ("*Taylor*") (U.S. Patent 5,308,621). Applicant respectfully traverses the 35 U.S.C. § 103(a) rejections as such

ATTORNEY DOCKET NO.
41758-P001P1C2

PATENT
Serial No. 09/990,611

rejections pertain to the cited claims. Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments to the claims and the following remarks.

The Examiner states that *Schinitzky, Murad, Herstein, and Taylor* were discussed in a prior Office Action (Applicant assumes the Examiner is referring to the Office Action mailed November 19, 2002) and that such discussion has been incorporated into the present Office Action. The Examiner further states that Applicant's arguments have been duly considered, but are deemed unpersuasive. The Examiner also notes that Applicant has argued that none of the prior art suggests having a pH of more than 3.5. However, the Examiner states that *Herstein* (column 10, lines 6-17) teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. See Office Action, pages 2 and 3.

In order to establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301 (Bd. Pat. App. & Int. 1993); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 U.S.P.Q. 657 (Fed. Cir. 1985). The legal conclusion of obviousness must be supported by facts. See *Graham v. John Deere & Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Where the legal conclusion is not supported by facts, it cannot stand. *Id.* A rejection based on § 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. The patentability of an invention is not to be viewed with hindsight or "viewed after the event." *Goodyear Company v. Ray-O-Vac Company*, 321 U.S. 275, 279, 64 S.Ct. 593, 88 L.Ed. 721 (1944). The proper inquiry is whether bringing them together was obvious and not, whether one of ordinary skill, having the invention before him, would find it obvious through hindsight to construct the invention. Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of the patent Applicants' invention without also providing objective evidence of the motivating

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

force which would impel one skilled in the art to do what the patent applicant has done. An Examiner's unsupported opinion is not objective evidence.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. See MPEP § 2143. See also *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Schinitsky discloses a composition comprising from about 2 to about 20% ascorbic acid, about 1 to about 10% tyrosine, and about 0.5 to about 5% zinc sulfate. See *Schinitsky*, column 2, lines 38-45. Applicant respectfully suggests that *Schinitsky* does not anticipate, disclose, or suggest Applicant's composition as disclosed in Applicant's independent claims 1, 18, and 26 and the claims depending therefrom. Applicant's claim 1 (previously presented) discloses a topical composition comprising: at least about 5.0% (w/v) ascorbic acid; and water, wherein the composition has a pH of more than 3.5. In addition, Applicant's claim 18 (previously presented) discloses a topical composition comprising: an aqueous solution including at least about 5.0% (w/v) ascorbic acid, wherein the composition has a pH of more than 3.5. See Applicant's claims 1 and 18. Applicant respectfully suggests that *Schinitsky* does not disclose or suggest various features of Applicant's claim(s) such as the composition having a pH of more than 3.5. Applicant further respectfully suggests that the Examiner has erroneously attempted to remedy the deficiencies of *Schinitsky* by combining with three other references, *Murad*, *Herstein*, and *Taylor*, to arrive at Applicant's claimed invention. Applicant also respectfully suggests that the Examiner has not presented any evidence regarding a motivation or suggestion to combine the references to arrive at Applicant's claimed invention.

Murad discloses a composition comprising at least four components: a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition

ATTORNEY DOCKET NO.
41758-P001P1C2

PATENT
Serial No. 09/990,611

metal component. *See Murad*, column 3, lines 25-35. Further, *Murad* prefers an embodiment where the composition is administered orally. In a preferred *Murad* embodiment, the composition is administered as a tablet or capsule having about 1 mg to 2,000 mg of *Murad* composition. *See Murad*, column 4, lines 39-50. Further, *Murad* discloses that although any suitable route of administration may be employed, oral administration is preferred. *See Murad*, column 8, lines 43-52. Further, all three routes of administration of the *Murad* composition disclosed in the *Murad* examples comprise orally administered forms such as capsules (*Murad* Example 1), soft gelatin capsules (*Murad* Example 2), and tablets (*Murad* Example 3). *See Murad*, column 10, lines 5-32. Further, *Murad* claim 1 discloses an orally administered pharmaceutical composition comprising the following *Murad* components: a sugar compound; a primary antioxidant component; at least one amino acid component; and at least one transition metal component. *See Murad*, claim 1.

Further, *Murad* does not anticipate, disclose or suggest a tyrosine compound and there is no disclosure or suggestion in *Murad* regarding pH. Applicant respectfully suggests that the *Murad* emphasis on oral administration, specifically capsules, soft gelatin capsules, and tablets, teach away from Applicant's composition having a pH of more than 3.5. Applicant also respectfully suggests that since *Murad* is preferably administered orally, pH is not a critical feature of the *Murad* composition and actually teaches away from Applicant's composition.

Applicant respectfully suggests that there is no motivation or suggestion to combine the *Schinitsky* composition comprising ascorbic acid, tyrosine, and zinc sulfate with no disclosure of an anti-inflammatory compound, an aminosugar, or pH levels with the specific four-component *Murad* composition preferably administered orally with no disclosure of tyrosine or pH levels to arrive at Applicant's claimed invention. Applicant respectfully suggests that the Examiner is utilizing *Murad* to erroneously remedy the deficiencies of *Schinitsky* regarding an aminosugar and pH levels. However, *Murad* only discloses the *Murad* sugar compound when utilized in the *Murad* composition that requires at least three additional elements such as the primary antioxidant, at least one amino acid component, and at least one transitional metal component, preferably in an oral form. Applicant also respectfully suggests that there is no reasonable

ATTORNEY DOCKET NO.
41758-P001P1C2

PATENT
Serial No. 09/990,611

expectation of success of combining *Schinitzky* with *Murad* to arrive at Applicant's claimed invention.

Herstein discloses a composition comprising two phases. The first *Herstein* phase is a powder phase containing ascorbic acid. The second *Herstein* phase is a liquid emulsion phase containing a stabilizing effective amount of an organoclay composition. See *Herstein*, column 2, line 65 - column 3, line 6. *Herstein* discloses in great detail the two phases. *Herstein* discloses that the liquid phase comprises an emulsifier that can be selected from various emulsifiers. See *Herstein*, column 4, line 31 - column 6, line 19. Further, *Herstein* does not anticipate or disclose an aminosugar or tyrosine. Further, *Herstein* discloses various anti-inflammatory agents that can be utilized in the *Herstein* composition that do not suggest an aminosugar and thus, *Herstein* actually teaches away from Applicant's use of an aminosugar. See *Herstein*, column 9, lines 52-64.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify the *Schinitzky* composition, comprising ascorbic acid, tyrosine, and zinc sulfate, with the *Murad* composition comprising four specific components preferably administered orally with no disclosure or suggestion of tyrosine or pH levels with *Herstein* that requires a two-part system comprising 5% powdered ascorbic acid and a 95% liquid phase that requires the use of the *Herstein* organoclay material.

Applicant respectfully suggests that the Examiner is using improper hindsight to remedy the deficiencies of *Schinitzky* with *Murad* and *Herstein*. The Examiner erroneously attempts to utilize the combination of *Schinitzky*, *Murad*, and *Herstein* to render obvious Applicant's claimed invention. Applicant respectfully suggests that the Examiner is utilizing improper hindsight by selecting features of the various compositions of the various references in an attempt to disclose each of the individual components of Applicant's claimed composition.

The Examiner has attempted to use *Herstein* to teach that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule. See Office Action, page 2. Applicant respectfully suggests that the Examiner is using improper hindsight based on Applicant's claimed invention to erroneously interpret *Herstein* regarding pH. *Herstein* discloses that preferably, the pH of the final *Herstein* composition should be maintained

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

within the range of 3.5 to 4.1. *Herstein* further discloses that the pH of the *Herstein* liquid phase is preferably maintained at 8.2 to 8.9 and more preferably 8.6 to 8.9. *Herstein* further discloses that organic ingredients can be emulsified in water along with the *Herstein* organoclay material. To this *Herstein* emulsion can be added the remaining ingredients and finally the pH can be adjusted to the desired level. *Herstein* further discloses that while the *Herstein* composition can be made generally in any order, it is important that the oil phase of the *Herstein* emulsion be established with the *Herstein* organoclay material therein. See *Herstein*, column 10, lines 6-43.

Applicant respectfully suggests that the *Herstein* disclosure regarding pH is directed to the *Herstein* composition comprising a specific two-phase system that requires a powdered ascorbic acid phase and a liquid phase comprising an emulsion comprising an organoclay material where the liquid phase is preferably maintained at a pH of 8.2 to 8.9. Applicant respectfully suggests that without the use of improper hindsight, *Herstein* cannot render obvious Applicant's features such as a composition having a pH of more than 3.5.

Applicant respectfully suggests that there is no motivation or suggestion to combine or modify the *Schinitzky* composition, comprising ascorbic acid, tyrosine, and zinc sulfate with no disclosure of an anti-inflammatory compound, an aminosugar, or pH levels, with the teachings of *Murad* of a composition comprising a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component, preferably administered orally with no disclosure or suggestion of tyrosine or pH levels, with the specific *Herstein* two-phase system comprising a liquid phase of an emulsion requiring an organoclay material that is maintained at a pH of 8.2 to 8.9, that only upon mixture of the two *Herstein* phases does the final pH disclosure become applicable, to render obvious Applicant's claimed invention.

Applicant respectfully suggests that the Examiner then utilizes a third reference, *Taylor*, in addition to *Murad* and *Herstein*, in a further attempt to remedy the deficiencies of *Schinitzky*. *Taylor* discloses a composition comprising a carrier and ascorbic acid in suspension within the carrier wherein the ascorbic acid comprises fine particles of ascorbic acid predominantly sized below 20 microns. See *Taylor*, column 2, line 67 – column 3, line 64, and claim 1. *Taylor* discloses a process comprising heating a mixture of a pharmaceutically acceptable carrier and the

ATTORNEY DOCKET NO.
41758-P001P1C2

PATENT
Serial No. 09/990,611

ascorbic acid followed by cooling, under specific *Taylor* conditions, such that the crystals that form on cooling are sufficiently fine to facilitate transdermal diffusion. Preferably, the crystals are predominantly sized less than 20 micrometers in average length of side. *See Taylor*, column 2, line 67 - column 3, line 15. Applicant respectfully suggests that *Taylor* requires a very specific process to provide for the *Taylor* ascorbic acid crystals less than 20 micrometers in size. Further, *Taylor* does not anticipate, disclose, or suggest an anti-inflammatory compound, an aminosugar, tyrosine, or pH levels.

Applicant respectfully suggests that the Examiner is utilizing improper hindsight to select various features of the references and combining the references without any motivation or suggestion to arrive at Applicant's claimed invention. Applicant also respectfully suggests that there is no reasonable expectation of success of combining *Schinitsky*, disclosing a composition comprising ascorbic acid, tyrosine, and zinc sulfate, with *Murad*, disclosing a composition comprising a sugar compound, a primary antioxidant component, at least one amino acid component, and at least one transition metal component, preferably administered orally, with the specific *Herstein* two-phase system, one phase of powdered ascorbic acid and the other phase of a specific emulsion comprising an organoclay material with a discussion regarding pH only relating to the specific *Herstein* two-phase system, with the *Taylor* disclosure of a two-part system comprising ascorbic acid crystals of up to 20 micrometers in size to arrive at Applicant's claimed invention. Applicant respectfully suggests that the Examiner is starting with *Schinitsky* and then, using improper hindsight, selecting the various features of Applicant's claimed composition from the various references to arrive at Applicant's composition.

Further, Applicant respectfully suggests that the very specific preparations of the compositions of the references utilized by the Examiner require specific components and specific concentrations prepared in specific ways and there is no indication that there would be any reasonable expectation of success of being able to combine these various referenced components to arrive at Applicant's claimed invention. Applicant respectfully suggests that the references, alone or in combination, do not anticipate, disclose or suggest Applicant's various claim features such as Applicant's high concentration of ascorbic acid and a composition having a pH of more than 3.5.

ATTORNEY DOCKET NO.
41758-P001PIC2

PATENT
Serial No. 09/990,611

Further, Applicant respectfully suggests that the individual references disclose specific compositions comprising specific components prepared specific ways due to the synergistic effects that each particular referenced composition provides that prevents the simple combination of the features of the various references to arrive at Applicant's claimed invention.

Applicant also respectfully suggests that the lack of motivation or suggestion to combine the references is further emphasized by the fact that the Examiner has not provided any basis for a motivation or suggestion to combine the references. The Examiner has stated that it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition. The Examiner has further stated that therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references. See Office Action mailed November 19, 2002, page 4.

Applicant respectfully suggests that the Examiner's general statements do not provide for the specific motivation or suggestion that is required to begin meeting the requirements for establishing a *prima facie* case of obviousness. Applicant respectfully suggests that the Examiner cannot rely on improper hindsight to search through the references to find each individual feature of Applicant's claimed invention and then merely state that such references can be combined to arrive at Applicant's claimed invention with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition.

In conclusion, Applicant respectfully requests that the Amendments to the Claims be entered. Applicant further respectfully requests that this Application be re-examined in light of the above amendments and remarks. Applicant further respectfully requests that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn and that the claims remaining in the Application be allowed.

No new matter has been added, merely amended to more particularly point out and distinctly claim the subject matter Applicant believes is inventive.

ATTORNEY DOCKET NO.
41758-P001P1C2

PATENT
Serial No. 09/990,611

Applicant notes that the Notice of Draftsperson's Patent Drawing Review (PTO-948) has not been received.

Since new claims have not been added, no additional filing fees are believed to be due. However, the Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C. (referencing number 41758-P001P1C2).

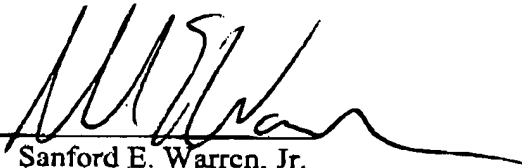
Enclosed is a Change of Correspondence Address to reflect the current address of Applicant's Attorney. Please reference Attorney Docket No. 41758-P001P1C2 on all further correspondence related to the present application.

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at (214) 745-5710.

Respectfully submitted,
WINSTEAD SECHREST & MINICK P.C.

Attorneys for Applicant

Dated: September 24th, 2003

By: 
Sanford E. Warren, Jr.
Reg. No. 33,219

P. O. Box 50784
1201 Main Street
Dallas, Texas 75270 - 0784
(214) 745-5710
Attorney's Docket: 41758- P001P1C2

OFFICIAL

**RECEIVED
CENTRAL FAX CENTER**

SEP 25 2003

DALLAS 1387187011
41758-P001P1C2 09/24/2003